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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/801,353	03/16/2004	Thomas Terwee	24793-24	2120

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DINSMORE & SHOHL, LLP  
1900 CHEMED CENTER  
255 EAST FIFTH STREET  
CINCINNATI, OH 45202

EXAMINER
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PREBILIC, PAUL B

ART UNIT	PAPER NUMBER
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3738

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/04/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary**

Application No.

10/801,353

Applicant(s)

TERWEE, THOMAS

Examiner

Paul B. Prebilic

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10 August 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-43 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-43 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 March 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/10/04</u> .   | 6) <input type="checkbox"/> Other: _____                          |

### ***Drawings***

The drawings are objected to under 37 CFR 1.84(h)(5) because Figure 2 show(s) modified forms of construction in the same view. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Specification***

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

### ***Claim Objections***

Claims 12, 16, 17, 20, 29, 31-36, 42 and 43 objected to because of the following informalities:

With regard to claim 12, it appears the claim fails to further limit the claim it depends from because it contains the same limitations already set forth.

With regard to claim 20, on line 2, "bing" appears to be a misspelling for the word "being."

With regard to claims 29, 42, and 43, the Markush language is unclear because of the multiple usages of the word "and." The Examiner suggests writing out the types of collagen as "type I collagen, type II collagen . . . " in order to overcome this objection.

With regard to claims 31-36, the word "comprises" appears to be improper in that additional features are being added. The Examiner suggests changing "comprises" to --  
-further comprises--- in order to overcome this objection.

With regard to claims 16, 17, 32, and 33, claims 16 and 17 appear to be the same scope as claims 32 and 33, respectively. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. With regard to claim 2, line 2, "the germinative zones of epithelial cells" lacks clear antecedence since epithelial cells are all along the capsule

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wall. Also, the "central parts" lacks clear antecedent basis. Furthermore, the "anterior and posterior surfaces" lack clear antecedent basis.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3, 9-12, 14, 18, and 19 are rejected under 35 U.S.C. 102(e) as being anticipated by Holmen (US 2002/0165522). Holmen anticipates the claim language where the method of inserting a composition after implant implantation is viewed as an alternative step; see paragraph 24; See also paragraphs 4 to 6, 2, 23, and 43 and the figures.

With regard to claim 2, the central parts could be outside the capsule in that the claim language is not limited in such a manner.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 4-8 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Holmen (US 2002/0165522).

With regard to claims 4-6, Holmen fails to disclose the type of needle used in the method as claimed. However, the Examiner asserts that utilizing such would have been considered clearly obvious to an ordinary artisan so as to prevent cytotoxic agent from being carried to other tissues by the needle

With regard to claims 7 and 8, Holmen teaches the use of a 3 mm opening but not a smaller one. However, the use of a smaller opening would have been obvious to an ordinary artisan because it would result in less trauma to the wound site.

With regard to claim 15, the use of an isotonic solution would have been obvious to an ordinary artisan in that it would not result in unwanted cell damage.

Claims 13 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Holmen (US 2002/0165522) in view of Huo et al (US 6,361,561). Holmen discloses the claimed method except for the use of injectable curable material for the lens. However, Huo teaches that such was known; see the abstract. Therefore, it is the Examiner's position that it would have been prima facie obvious to an ordinary artisan to utilize an injectable crosslinkable polymer as the IOL of Huo for the same reasons that Huo uses the same.

Claims 20-25 and 38-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Holmen (US 2002/0165522) in view of Spruce et al (US 5,968,824). Holmen discloses the claimed method except for the use a nucleic acid molecule for the cytotoxic agent as claimed. However, Spruce teaches that it was known to use p53, a

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nucleic acid cytotoxic agent in similar methods of the art; see column 8, lines 12-19 and column 3, line 50 et seq. Therefore, it is the Examiner's position that it would have been *prima facie* obvious to an ordinary artisan to utilize p53 as the cytotoxic agent of Holmen for the same reasons that Spruce utilizes the same.

Claims 16, 17, 26-36 and 42-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Holmen (US 2002/0165522) in view of Green et al (WO 02/15828). Holmen discloses the claimed method except for the use other various agents for the cytotoxic agent as claimed. However, Green teaches that it was known to utilize the various agents claimed as the cytotoxic agent within the art; see pages 10 to 13. Therefore, it is the Examiner's position that it would have been *prima facie* obvious to an ordinary artisan to utilize the various agents claimed as the cytotoxic agent of Holmen for the same reasons that Green utilizes the same.

### **Conclusion**

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action if the application is not stored in image format (i.e. the IFW system) or published.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Paul B. Prebilic whose telephone number is (571) 272-4758. He can normally be reached on 6:30-5:00 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Paul Prebilic  
Primary Examiner  
Art Unit 3738